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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Luc UYLENBROECK et al.

Serial No. 09/375,514

Filed August 17, 1999

Docket No. 00292/IPD/9909-060

A METHOD FOR PREVENTING THE
ONSET OF ASTHMA



#5
AQJ
10/13/99

INFORMATION DISCLOSURE STATEMENT

RECEIVED

Assistant Commissioner for Patents
Washington, DC 20231

SEP 16 1999

TECH CENTER 1600/2900

Sir:

Pursuant to the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, Applicants request consideration of (X) the references listed on the attached Form PTO-1449 and/or () the additional information identified below in paragraph 4. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior parent application Serial No. .

1. This Information Disclosure Statement is submitted:

- a. (X) within 3 months of the filing date of the above-identified application, or
() within 3 months of entry into National stage prosecution of an International application, or () before the mailing date of the first Office Action on the merits, and thus:

(X) no certification and/or fee is required.
- b. () after the events of above paragraph 1a and prior to the mailing date of a final Office Action or Notice of Allowance, and thus:

() the certification of paragraph 2 below is provided,
or
() a fee of \$240.00 is enclosed.

- c. ☐ after the mailing date of a final Office Action or a Notice of Allowance and prior to payment of the issue fee, and thus:
- ☐ the certification of paragraph 2 below is provided,
- and
- ☐ the Petition of paragraph 3 below is provided and \$130.00 fee therefor is enclosed.

2. It is hereby certified

- ☐ that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
- ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Petition under 37 CFR 1.97 for consideration of this Information Disclosure Statement is hereby made.

4. ☐ Consideration of the following additional information (including any co-pending or abandoned U.S. application, prior uses and/or sales, etc.) is requested:

5. ☐ For each non-English language reference listed on the attached Form PTO-1449:
- ☐ reference is made to an English language translation or abstract submitted herewith, and/or
- ☐ reference is made to a foreign patent office search report (in the English language) submitted herewith, and/or
- ☐ reference is made to an English language translation of a foreign patent office search report submitted herewith, and/or

() reference is made to the concise explanation contained in the specification of the present application at page(s) , and/or

(X) reference is made to the concise explanation set forth below:

1 - Document 3 on page 2 of the search report

Trieloff, I (TW PADIATRIE. 1995, 8/1. 61-62) briefly describes the background of the ETAC (ETAC : Early Treatment of the Atopic Child) study protocol, based on interviews with German scientists in the field of allergy. This document contains a summary of hitherto available prevention measures, i.e. allergen avoidance (mites, pets) and the rationale behind the start of the ETAC study : a double-blind placebo-controlled trial of cetirizine in infants (12-24 months of age) at high risk of asthma development due to a family history of asthma/allergy and the presence of atopic dermatitis but no evidence of asthma - i.e. an attempt of primary prevention of asthma. The asthma risk was estimated to 50% in this group of children.

2 - Document 4 on page 2 of the search report

Allergo J. Vol. 4, 7/95, 390-391 (1995) describes preventive measures, like the document of Trieloff, I.. Primary prevention means measures instituted before the onset of disease, secondary prevention intervention once there are symptoms and/or signs of disease. Again, the rationale behind pharmacological intervention with cetirizine to prevent development of asthma in infants free from asthma, but at high risk thereof, and the protocol of the ETAC study are presented.

3 - Document 1 on page 3 of the search report

Castello D. (RIVISTA ITALIANA DI PEDIATRIA (1998), 24/4, 824-827) summarizes the literature available regarding the prevention and some risk factors of asthma in babies. Some prevention measures are listed as Omega 3 fatty acid intake, passive smoking....

4 - Document 2 on page 3 of the search report

Bidat E. et al. *Concours Médical*, (1991), 113/34, 3021-3026 review the medical treatment of asthma. Cetirizine is more an anti allergic drug and not an anti-asthma medication.

5 - Document 3 on page 3 of the search report

Businco I. Et al. (*Minerva Pediatrica* (1997), 49 (10) 477-81) relate to the risk factor of asthma e.g. Atopic dermatitis and sensitization to egg.. Regarding the inhaled allergens, the sensitization to house dust mite followed by pollen sensitization is in relation to dermatological or pulmonary manifestations. The author suggests the use of specific immunotherapy.

6 - Document 4 on page 3 of the search report

Schwarz, B , *PHARM ZGT*, 138/20 (1993) summarizes a symposium held in Potsdam April, 1993, aimed at position the use of antihistamines in the treatment of allergy in children (i.e. secondary prevention). This document teaches mechanisms of allergic inflammation and the effect of cetirizine as an histamine H1-antagonist and also as an anti-inflammatory agent, due to its capacity to reduce traffic of eosinophilic leukocytes. The effect of cetirizine in the treatment of asthma (including prevention of symptoms and signs of asthma in children already having asthma, i.e. secondary prevention) was described as equal to or better than that of Dinatriumcromoglicate.

The document also summarised the great need of extended research in the field of allergy to identify causes of the recent rise in the prevalence of allergic diseases.

7 - Document 3 on page 5 of the search report

Matsubara S. et al. , *Japanese Pharmacology and therapeutics*, (1997) 25/4, 31-36 describe a study on guinea pigs. They investigated the effect of a new anti asthma drug in a animal model using cetirizine as one of the comparator in a animal pharmacologic model of hyper bronchial reactivity.

6. ☐ Applicant also offers the following comments for the Examiner's consideration:
7. ☒ Also enclosed is a copy of the European Search Report citing these references.

Respectfully submitted,

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